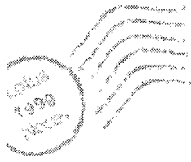
201-14519



NCIC HPV
Sent by: Mary-Beth Weaver

06/03/2003 11:21 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on Reaction Product (Cyclododecanol/ Cyclododecanone/Nitric Acid), High-Boiling Fraction also known as Corfree (R) Ml (CAS# 72162-23-3)

Richard_Denison@environmentaldefense.org on 05/29/2003 02:44:49 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, Edwin.L.Mongan-I@usa.dupont.com
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Reaction Product (Cyclododecanol/ Cyclododecanone/Nitric Acid), High-Boiling Fraction also known as Corfree (R) Ml (CAS# 72162-23-3)

(Submitted via Internet 5/29/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Edwin.L.Mongan-1@usa.dupont.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Reaction Product (Cyclododecanol/ Cyclododecanone/Nitric Acid), High-Boiling Fraction also known as Corfree (R) Ml (CAS# 72162-23-3).

Corfree Ml is the reaction product (high boiling fraction) of cyclododecanone, cyclodecanol and nitric acid and it is used as in the production of corrosion inhibitors for metalworking fluids, engine coolants and industrial cleaners. No data are provided on the presence or absence of Corfree Ml in these industrial products, so it is difficult to evaluate the potential for environmental or consumer exposures.

The test plan and robust summary for Corfree Ml were prepared by E.I. du Pont Nemours and Company. This material is a complex mixture comprised of dodecanedioic acid (DDA) (38-49%), undecanedioic acid (31-38%), sebacic acid (5-7%), other dibasic acids (9-19% and other organics (7-11%). In cases where SIDS data are not available for Corfree Ml, the sponsor proposes to use surrogate data from DDA to fulfill HPV requirements; no additional studies are proposed. However, Corfree Ml and DDA do not behave in a similar manner in some biological tests, most notably the biodegradation studies. Therefore, we do not agree that DDA is a reliable surrogate for all HPV endpoints and we recommend that fugacity studies, a combined repeat dose/reproductive/ developmental toxicity study and possibly other studies be conducted using Corfree Ml as the test substance. Specific comments are as follows:

1. Biodegradation data presented in the robust summary indicate that DDA is readily biodegradable but that Corfree Ml is not. This finding indicates that there are constituents in Corfree Ml that are quite resistant to biodegradation. The identity of the persistent chemicals is not indicated, but they are most likely found in the "other organics" component. We recommend that the identity of chemicals present in the "other organics" fraction be determined and made available, and that environmental fate studies be conducted on those chemicals as well as on Corfree Ml.

2. Depending on the outcome of the environmental fate studies, it may be necessary to conduct ecotoxicity testing (for acute toxicity in fish and aquatic plants) on individual constituents as well as on Corfree Ml.

3. No additional mammalian acute toxicity studies are needed.

4. Genotoxicity studies may be needed on Corfree Ml and individual constituents depending on the outcome of recommended studies indicated in our points 1 and 2.

5. Since Corfree Ml contains individual constituents possessing biological properties that differ from those of DDA, it is not appropriate to use DDA as a surrogate for repeat dose, reproductive and developmental toxicities. Therefore, we recommend that a combined repeat dose/reproductive/developmental toxicity study be conducted on Corfree Ml.

Thank you for this opportunity to comment.

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Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense